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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/597,179 | 06/20/2000 | Maura Rooney | BSP2102US02 | 5883 |

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| EXAMINER |
|---|
| HINDENBURG, MAX F |

| ART UNIT | PAPER NUMBER |
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| 3736 | 20 |

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/597,179 | Applicant(s) ROONEY ET AL. |
|---|---|---|
| | Examiner Max Hindenburg | Art Unit 3736 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21,25,26,28-30 and 32-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,25,26,28-30 and 32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 22, 25, 26, 28, 30, 32-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986) in view of McMahon (485) and Slaikeu et al. Morrison (986) discloses a guidewire having an elongate tapered core of stainless steel or other materials having a continuous unitary coil, 33 in figure 4, of stainless steel that surrounds the entire length of the core or along the length of the core near the proximal and distal ends, and a tip 36 of a radio-paque material. The coil has a pitch that varies at least once, see the distal end of the coil in figure 4. The coil has a coating of a lubricious material and is circular in cross-section. Morrison does not teach the core is of a nickel-titanium alloy (Nitinol) or that the tip is of a polymeric material. McMahon (485) teaches a guidewire having a polymeric tip 20 for preventing trauma to the patient upon insertion of the guidewire into the body. Slaikeu et al. teach a guidewire with an elongate core made of stainless steel or a nickel-titanium alloy (Nitinol) for strength and flexibility, col. 3, lines 63-66. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the guidewire of Morrison as shown by McMahon to make the tip of a polymeric material to prevent trauma to the patient and as shown by Slaikeu et al. to make the core of a nickel-titanium alloy for strength and flexibility.

3. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986) in view of McMahon (485) and Slaikeu et al. as applied to claims 22, 25, 26, 28, 30, 32-35 and 38 above, and further in view of Beisel. Morrison, McMahon and Slaikeu et al. disclose the limitations above, but do not teach the use of a precipitation hardened alloy as the coil material. Beisel discloses a precipitation hardened alloy as the coil material for aiding guidewire insertion into a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the guidewire of Morrison as shown by Beisel because the precipitation hardened alloy would increase the coil stiffness and enhance torqueability.

4. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986) in view of McMahon (485) and Slaikeu et al. as applied to claims 22, 25, 26, 28, 30, 32-35 and 38 above, and further in view of Whitbourne (517). Morrison, McMahon and Slaikeu et al. disclose the limitations above, but do not teach the use of a colored coating. Whitbourne (517) teaches the use of a colored coating with various medical devices such guidewires to enhance the performance of the devices, col. 4, lines 2-11. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the guidewire of Morrison as shown by Whitbourne (517) to make the coating colored to enhance the performance of the guidewire by assisting in the identification of the guidewire.

5. Claims 37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986) in view of McMahon (485) and Slaikeu et al. as applied to claims 22, 25, 26, 28, 30, 32-35 and 38 above, and further in view of Hodgson. Morrison,

McMahon and Slaikeu et al. disclose the limitations above, but do not teach the use of a coil with a rectangular cross-section, a coil made of multifilar wire or a coil made by cross-wound. Hodgson teaches a guidewire having a coil with rectangular, cross-wound multifilar construction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the guidewire of Morrison as shown by Hodgson to make the coils of a rectangular, cross-wound multifilar construction to enhance torqueability.

6. Applicant's arguments filed April 7, 2003 have been fully considered but they are not persuasive. Applicant argues none of the references show a continuous, unitary coil. However, as set forth above, Morrison teaches this feature in his 2nd embodiment shown in figure 4. The remaining claimed limitations are all also met as set forth above. This office action is not made final because claim 25 was previously indicated allowable, but is now rejected.

7. Any questions relating to this application can be addressed to Max Hindenburg who can be reached at (703) 308-3130.

Max Hindenburg

SPE 3736

June 26, 2003

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